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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/026,882	02/19/98	ROSENBLUM	M D5442C/CIP

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HM22/0301

EXAMINER

HUFF, S

ART UNIT

PAPER NUMBER

1642

*16*

DATE MAILED: 03/01/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/026,882

Applicant(s)

Rosenblum

Examiner

Sheela J. Huff

Group Art Unit

1642



☒ Responsive to communication(s) filed on Jan 11, 2001

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-17 is/are pending in the application.

Of the above, claim(s) 1-7, 16, and 17 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 8-15 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☒ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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**DETAILED ACTION**

***Response to Amendment***

***Continued Prosecution Application***

1. The request filed on 1/11/01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/026882 is acceptable and a CPA has been established. An action on the CPA follows. Claims 1-17 are pending.

Claims 1-7 and 16-17 are withdrawn from consideration as being drawn to a non-elected invention.

Claims 8-15 are currently under consideration.

***Response to Arguments***

***Oath/Declaration***

2. The oath or declaration remains defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not state that the person making the oath or declaration in a continuation-in-part application filed under the conditions specified in 35 U.S.C. 120 which discloses and claims subject matter in addition to that disclosed in the prior copending application, acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

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Applicant's new declaration filed 5/26/00 is still defective. It is noted that the instant application is CIP of 08/702205 and the new declaration must clearly state this.

experimentation would be required by one skilled in the art to make and use the instant invention.

The serial no. of the FAXed declaration are unreadable and therefore the declaration remains defective.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 8-15 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Tanimoto et al, Leukemia, vol. 3 p. 339 (1989) or Scheinberg

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et al, Leukemia, vol. 3 p. 440 (1989) in view of Thorpe et al, Immunological Reviews vol. 62 p. 119 (1982) and Andrews et al Blood, vol. 62 p. 124 (1983) and Rosenblum et al US 5631348 (filed 8/14/90). The reasons for this rejection are of record in paper no. 7, mailed 12/27/99.

Applicant argues that the references do not teach the conjugates. The references alone do not teach the conjugate--the references in combination do. Applicant has not rebutted the Examiner's reason for combining the references.

Applicant argues that the references do not show the conjugate would be effective. In view of Thorpe et al which shows that conjugates containing gelonin are effective killers and in view of the showing in Andrews et al that Mab's reactive with CD33 can be used to treat leukemia and in view of Tanimoto et al and Scheinberg et al which shows that M195 is directed to CD33, one of ordinary skill would reasonable expect that the conjugate of M195 and gelonin would be an effective killer.

Applicant argues that the conjugates are not enabled. making conjugates is very well known in the art (Thrope et al). M195 clearly binds to cancer cells (primary ref and Andrews et al). Gelonin is clearly toxic to cells and is routinely used in immunotoxins(Thorpe et al). Thus, forming a conjugate using a ab known to bind cancer cells with a known toxin using known and routine methods would result in a conjugate toxic to the cancer cells and since all the methods are routine no undue experimentation is needed.

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6. Claims 8-15 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Scheinberg US 5730982 (filed 12/14/89) in view of Thorpe et al, Immunological Reviews vol. 62 p. 119 (1982) and Andrews et al Blood, vol. 62 p. 124 (1983) and Rosenblum et al US 5631348 (filed 8/14/90). The reasons for this rejection are of record in paper no. 7, mailed 12/27/99. Applicant's arguments have been addressed above.

***Conclusion***

7. No claim is allowed.
8. All claims are drawn to the same invention claimed in the parent application prior to the filing of this Continued Prosecution Application under 37 CFR 1.53(d) and could have been finally rejected on the grounds and art of record in the next Office action. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing under 37 CFR 1.53(d). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J. Huff whose telephone number is (703) 305-7866. The Examiner can normally be reached on Monday and Wednesday from 6:30am to 12:30pm and Thursday from 6:30am to 3:00pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Tony Caputa, can be reached on (703)308-3995.

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The FAX phone number for the group is (703)308-4242.


Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [anthony.caputa@uspto.gov].

All Internet e-mail communications will be made of record in the application file.

**PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122.** This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-0196.

Sheela J. Huff  
March 1, 2001

  
Sheela J. Huff  
Primary Examiner